REMARKS

Applicants' representatives thank Examiner Davis and Primary Examiner Ungar for the interview of July 15, 2005. The amendments and remarks herein are made in accordance with our interview. Claims 44 and 56 are amended to delete the phrase "a chimeric antibody". Upon entry of the present amendments, claims 41-64 will be pending. No new matter has been added.

Deposit Requirement

The Examiner has maintained the request for an affidavit or declaration regarding the deposit. *See,* Paper No. 20050510, page 2. While applicants submit that the statement made in the response sent March 2, 2005 fully satisfies the requirements under the 37 C.F.R §§ 1.803-1.809, in accordance with the Examiner's request, the following declaration is respectfully submitted:

Availability of the Deposit

> Human Genome Sciences, Inc., the assignee of the present application, has deposited biological material under the terms of the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure with the following International Depository Authority: American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, Virginia 20110-2209 (present address). The deposit was made on October 11, 1994, accepted by the ATCC, and given ATCC Accession Number 75913. In accordance with M.P.E.P. § 2410.01 and 37 C.F.R. § 1.808, assurance is hereby given that all restrictions on the availability to the public of ATCC Accession Number 75913 will be irrevocably removed upon the grant of a patent based on the instant application, except as permitted under 37 C.F.R. § 1.808(b). The assignee of the present application will replace the deposited biological material should the deposited material be destroyed or rendered non-viable.

In view of the above affirmation and explanation, attested to by the signature (below) of the Attorney for the Applicants, it is respectfully requested that the rejection of claim 53 under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejection of Claims 44 and 56 under 35 U.S.C. §112, second paragraph

The Examiner has maintained the rejection of claims 44 and 56 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for the use of the language "a chimeric antibody". *See,* Paper No. 20050510, page 3. Applicants have amended claims 44 and 56 to

remove the objected language. Accordingly this rejection has been obviated and should be withdrawn.

Rejection of Claims 41-64 under 35 U.S.C. § 112, first paragraph

The Examiner has maintained the rejection of claims 41-64, under 35 U.S.C. § 112, first paragraph, for lack of enablement. *See*, Paper No. 20050510, pages 3-8. More specifically, the Examiner alleges that "it is not predictable that one could use the claimed polypeptide for detecting metastasized prostate cells, because it is unpredictable that metastasized prostate cells still express the claimed sequence". See *id.*

Applicants respectfully disagree and traverse.

Preliminarily, Applicants point out that the pending claims are directed to methods of detecting prostatic specific reductase (PSR) protein using PSR specific antibodies and thus do not require the PSR proteins to have a particular recited utility. Accordingly, in order to fully enable the claimed methods as required by 35 U.S.C. § 112, the proteins detected according to the claimed methods need only have a single use (e.g., as an enzymatic reductase), and the specification need only enable a person of ordinary skill in the art to practice the claimed methods without undue experimentation.[1]

Applicants submit that the enzymatic reductase activity of PSR protein is a specific, substantial and credible use. Additionally, one of ordinary skill in the art, when armed with the disclosure of the specification, would require no more than routine experimentation to practice the claimed methods. Therefore, Applicants assert that the claimed methods are fully enabled irrespective of, for example, the expression profile of PSR protein in normal and metastasized prostate tissue.

The specification discloses that PSR protein has enzymatic activity as a reductase. *See, e.g.,* last sentence in paragraph 2. The reductase activity of the PSR protein, first identified by Applicants and disclosed in the instant application, is corroborated by the post-filing disclosures of Lin *et al.*, (*Cancer Research* 61:1611-1618 (2001); submitted as Reference AR in Applicants' Information Disclosure Statement of December 19, 2001 and resubmitted herewith as Exhibit A) and Kedishvili *et al.*, (*Journal Biological Chemistry* 277(32):28909-28915 (2002); attached herewith as Exhibit B). As noted in Applicants' reply

[1] Applicants need to show utility for only one disclosed purpose. See Raytheon Co. v. Roper Corp., 220 USPQ 592 (Fed. Cir. 1983, *cert. denied*, 469 U.S. 835 (1984); Ex parte Lanham, 121 USPQ 223 (Pat. Off. Bd. App. 1958).

sent March 2, 2005, the PSR protein disclosed in the present application and the PSDR1 protein disclosed in Lin *et al.*, share greater than 98% sequence identity (see e.g., alignment submitted in Applicants' reply sent March 2, 2005, and resubmitted herewith as Exhibit C). As can be seen in Figure 2 of Lin *et al.* (page 1615) and in the alignment provided in Exhibit C, PSR and PSDR1 both contain the conserved sequence segments (i.e., GlyXXXGlyXGly and TyrXXXLys), which are present in members of the short-chain dehydrogenase/reductase enzyme family. *See* Figure 2 legend of Lin et al. for conserved sequence segments. Furthermore, the minor sequence differences between PSR and PSDR1 do not appear to be at positions conserved amongst the portions of the proteins aligned in Figure 2 of Lin *et al.* Accordingly, Lin *et al.*, support the proposition that PSR and PSDR1 have the same enzymatic activity, despite having minor sequence differences.

As further support, Kedishvili *et al.* demonstrate that PSDR1 has reductase activity (*See, e.g.,* abstract). Thus, the publications of Lin *et al.* and Kedishvili *et al.* corroborate that PSR has enzymatic activity as a reductase.

Applicants respectfully submit that the enzymatic reductase activity of PSR is specific, substantial, and credible. Moreover, the skilled artisan, enlightened by the teaching of the present specification and the high level of skill in the art, would be more than capable of routinely making and using an antibody that specifically binds the PSR protein to routinely practice the claimed methods of detecting PSR protein.

Furthermore, Applicants reemphasize that the relevant legal inquiry with respect to enablement of the pending claims is not whether the antibodies used according to the claimed methods would bind and therefore detect variant PSR proteins, but rather whether the claimed methods involving use of antibodies that specifically bind the polypeptides of SEQ ID NO:2 or ATCC Deposit No. 75913 to detect PSR in a biological sample can be confirmed, without undue experimentation, by following procedures either described in the specification or otherwise known in the art. For the reasons stated above, Applicants submit that the claimed methods are fully enabled.

In summary, Applicants submit that due to: (1) the availability of routine methods in the art for generating antibodies; (2) the availability of routine methods for detecting the presence of PSR protein; (3) the teachings in the specification and the corroborating evidence that PSR is an enzymatic reductase; and (4) the high level of skill in the field of immunology and molecular biology, one skilled in the art could routinely generate antibodies and then use these antibodies to detect PSR protein and thus satisfy the limitations recited in the claims.

In light of the above remarks, it is clear that the specification as originally filed fully enables the claimed methods. Accordingly, Applicants respectfully request that the rejection of claims 41-64, under 35 U.S.C. § 112, first paragraph, for lack of enablement, be reconsidered and withdrawn.

CONCLUSION

Applicants respectfully request that the above remarks be made of record in the file history of the instant application. Applicants respectfully submit that the present application is now in condition for allowance. A Notice of Allowance is earnestly solicited. If, in the opinion of the Examiner, a telephone conference would expedite prosecution, the undersigned can be reached at the telephone number indicated below.

No fee is believed to be due in connection with this filing, however if applicants are in error, please charge any fee deemed necessary to Deposit Account No. 08-3425.

Dated: September 23, 2005

Respectfully submitted,

By _____
Kenley K. Hoover
Registration No.: 40,302
HUMAN GENOME SCIENCES, INC.
Intellectual Property Dept.
14200 Shady Grove Road
Rockville, Maryland 20850
(301) 610-5771

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